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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,347	07/31/2001	Noel John de Souza	U 013560-1	2749

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26 WEST 61ST STREET  
NEW YORK, NY 10023

EXAMINER
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SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/16/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/919,347

Applicant(s)

DE SOUZA ET AL.

Examiner

D. Margaret Seaman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 59-197 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59-197 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

Claims 1-58 have been canceled per paper #13, dated 24 March 2003. Claims 59-197 are before the Examiner.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 59-197 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-58 are ambiguous due to the definition of R7 when one of the rings (see page 4 lines 1-15), R7 is missing the terminal part. For example -N(ring)-W-?. If this is meant to be R7 together with one of R6 or R5 make these spiro combinations, then this needs to be clearly stated. Correction is required.

#### *Claim Rejections - 35 USC § 102/103*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 59-197 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ledoussal (US Patent #6,329,391).

Ledoussal teaches compounds such as formula 1 that work against resistant microbials. Ledoussal teaches the compounds can be used with other active ingredients. The method of inhibiting efflux pump is inherent in Ledoussal due to both Ledoussal and the instant applications treating microbial infections.

Applicants argue that Ledoussal teaches away from efflux pump inhibitors. Column 3 lines 8-9, such inhibition would increase the activity of the antimicrobial activity of a compound. Column 37 lines 45-52 teach the combination of the compounds of Ledoussal with other active ingredients. The ability of Ledoussal's compounds to be efflux pump inhibitors is inherent unless applicant can show that the compounds of Ledoussal are not efflux pump inhibitors. The same conditions are treated with the same result. Due to this, the rejection is maintained.

6. Claims 59-197 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ito (US Patent #5,859,026).

Ito teaches compounds such as formula in the abstract, alone or in combination, as antimicrobial agents. The method of inhibiting efflux pump is inherent in Ito due to both Ito and the instant applications treating microbial infections.

Applicant argues that Ito's compounds increase chromosomal abnormality. However, column 24 lines 65-67, Ito states that the chromosomal abnormality is significantly decreased. Also, Ito teaches the combination of two or more active compounds by column 13 lines 35-36. The ability of the compounds of Ito to treat microbial infections by use of an antimicrobial agent and an efflux pump inhibitor since the compounds of Ito are inherently the same compounds as are instantly claimed.

7. Claims 59-197 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Miyake (US Patent #5,889,009).

Miyake teaches compounds, alone or in combination, as antimicrobial agents. The method of inhibiting efflux pump is inherent in Miyake due to both Miyake and the instant applications ultimately treating microbial infections.

The instantly claimed efflux pump inhibitors are coextensive with the compounds of the prior art. Due to this, the compounds of the prior art are inherently

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efflux pump inhibitors and antimicrobial agents. The compounds of the prior art and the instantly claimed compounds treat the same conditions. The compounds of the prior art can be mixed with other active ingredients as is instantly claimed. Since the compounds used in the pharmaceutical activities overlap significantly and have the same outcomes (treating microbial infections) in the same populations, it is not seen, absent a showing, where the prior art compounds are not inherently the same as what is instantly claimed.

### *Conclusion*

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

dms  
May 12, 2003